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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/092,095	03/06/2002	Brian Bates	8627-051	8504

7590

08/18/2004

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EXAMINER

WEBB, SARAH K

ART UNIT PAPER NUMBER

3731

DATE MAILED: 08/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/092,095	Applicant(s) BATES, BRIAN	
	Examiner Sarah K Webb	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 June 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>6/18/02</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 1,2,4-8,10-13,18,19,21,22,24 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No. 6,231,597 to Deem et al.

See Figures 4 and 11A. The support frame (14) of the stent is a single wire, as most clearly seen in Figure 1. The term “substantially” was given the broadest reasonable interpretation. The circumference of the stent of Deem is considered to have a “substantially uniform circumference.” The circumference of a device is determined by its radius, and the radius of the Deem stent does not vary over its length. A graft material (104) is disposed on a portion of the support frame and only extends over approximately half the circumference of the stent. Deem explains that the material (104) is formed of typical graft material, such as PTFE and is attached by means such as adhesives (column 5, lines 45-55). Regarding claim 6, some of the adjacent curved regions located at each end of the stent extend beyond each other. The term

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"interleaved" in claim 18 does not require the curved regions to extend beyond one another.

Regarding the limitation "formed from a pattern in a sheet" in claims 7 and 21, this is only a product by process recitation. Whether a product is patentable depends on whether it is known in the art or it is obvious, and is not governed by whether the process by which it is made is patentable. Therefore, the limitation was not given patentable weight.

2. Claims 1-4, 7, 9, 28, and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 6,036,725 to Avellanet.

Avellanet discloses a stent in Figure 1 that includes a single wire support frame (30). Graft material (16) is disposed about a portion of the circumference. Avellanet explains that portions (16) include graft material, such as PTFE (column 6, lines 50-60). The stent can engage the entire inner circumference of a vessel. The graft material (16) extends only a portion of the length of the frame and about ½ the circumference. The device can be deployed with a balloon catheter (Fig. 22) and with a retractable sheath (44).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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3. Claims 30-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deem in view of US Patent No. 6,080,191 to Summers.

Deem fails to form the support frame with a longitudinal support. Summers discloses a stent in Figure 1 that is similar in structure to the support frame of Deem. In Figure 21, Summers shows an alternate form of the stent with a longitudinal support. Both structure have ring segments joined by curved sections. It would have been obvious to one of ordinary skill in the art at the time the invention was made to include a longitudinal support in the frame of Deem, as Summers teaches that this is alternate form a stent that has ring segments joined by curved sections.

4. Claims 14,20, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deem.

The graft of Deem extends half the circumference of the frame instead of only one-fourth the circumference. It would have been an obvious matter of design choice to reduce the length of the graft around circumference of the frame, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art.

5. Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Deem in view of Summers.

The graft of Deem, as modified by Summers, extends half the circumference of the frame instead of only one-fourth the circumference. It would have been an obvious matter of design choice to reduce the length of the graft around circumference of the frame, since such a modification would have involved a mere change in the size of a

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component. A change in size is generally recognized as being within the level of ordinary skill in the art.

6. Claims 15 – 17 and 25 –27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deem in view of US Patent No. 6,464,720 to Boatman et al.

Deem includes all the limitations of the claims, except for three radiopaque markers adjacent to the edge of the graft material. The edge of the graft material is at the edge of the stent frame, so radiopaque markers at the edge of the stent frame would meet this limitation. Boatman discloses a wire frame stent. Boatman teaches that it is particularly useful to have three radiopaque markers positioned at both the proximal and distal ends of the stent so that it can be clearly viewed to determine its exact location (column 19, lines 21-67). As shown in Figure 28, three radiopaque markers (102,103,104) are located at the edge of the stent frame. It would have been obvious to one of ordinary skill in the art at the time the invention was made to include three radiopaque markers at the edge of the stent frame of Deem, as Boatman teaches that this arrangement of radiopaque markers aids in the determination of the exact location of the stent in the body.

7. Claims 36-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deem in view of Summers, as applied to claim 30 above, and further in view of Boatman. See rejection (6) above.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarah K Webb whose telephone number is (703) 605-1176. The examiner can normally be reached on Mon-Fri 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, McDermott or Shaver can be reached on (703) 308-0858. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SKW
08/13/04

SKW

Julian W. Woo

JULIAN W. WOO
PRIMARY EXAMINEE